

Title. Anticipatory Care Planning Intervention for Older Adults at Risk of Functional Decline: A Primary Care Feasibility Study

Main objective. To determine the feasibility of a cluster randomised trial to evaluate the implementation and outcomes of Anticipatory Care Planning (ACP) in primary care to assist older adults identified as at risk for functional decline by developing a personalized support plan.

Questions.

- 1) Determine the optimal mechanisms for intervention delivery;
- 2) Assess patients, their family carers and health care providers perception of the appropriateness, benefits and convenience of the ACP intervention;
- 3) Determine recruitment / retention rates and outcome variability to inform sample size calculations for a full trial;
- 4) Identify optimal recruitment strategies for general practices and patients for a full trial;
- 5) Determine outcome measures and economic assessment strategies for a full trial;
- 6) To determine optimal procedures for conducting a cluster randomised trial.

Study outcomes. The feasibility study will provide a detailed evidence-based assessment on the potential impact of the ACP intervention on patient quality of life, mental health, healthcare utilisation, costs, perception of person centred care, and reduction of potentially inappropriate prescribing in an all Ireland context. Study outcomes will include:

1. Methodological and statistical considerations for a definitive randomized trial.
2. Potential improvements in care for the person at risk of functional decline including:
 - a. Improved ability to assess care needs and respond more appropriately.
 - b. Enhanced decision making among patients regarding care.
 - c. Improved communication between healthcare providers, patients and family carers on goals of care.
3. Considerations on implementation and sustainability of the intervention situated in primary care.
4. Formation of strategic cross-border partnerships committed to further evaluation via a definitive cluster randomised trial.

Background evidence. The provision of high quality, comprehensive care for older adults is becoming increasingly challenging because of the ageing of society, shortages of healthcare providers, and rising healthcare costs (1-4). Within this landscape primary care is increasingly seen as potentially the optimal context to deliver care for people with complex care needs because it is accessible, efficient and can address inequalities related to socioeconomic deprivation. However the current approach in primary care is reactive and fragmented and does not fully meet the needs of older people (3,5,6). A transition toward more proactive primary care has been proposed (3,5,6). Proactive primary care prescribes a timely start in managing a patient's long-term conditions by facilitating anticipatory care planning in order to meet patient wishes and needs, relieve symptoms, and prevent future symptoms and problems. A core aspect of anticipatory care is personalized care planning (7). This aims to ensure that individuals' values and concerns shape the way long-term conditions are managed. Instead of focusing on a standard set of disease management processes determined by health professionals, this approach encourages patients to select treatment goals and to work with clinicians to determine their specific needs for treatment and support. Personalized care planning is anticipatory (forward looking), involving a negotiated series of discussions between a patient and a health professional to clarify goals, options and preferences, and to develop an

agreed plan of action based on this mutual understanding (7).

Proof of concept that personalized care planning leads to better outcomes for adults with long-term health conditions was recently demonstrated in a systematic review (7). In this review, nineteen studies were identified that included a total of 10,856 participants with conditions such as diabetes, mental health conditions, heart failure, kidney disease and asthma. The authors concluded that personalized care planning led to improvements in physical and psychological health status, and people's capacity to self-manage their condition when compared to usual care. While these findings are encouraging, more trials are required to check the robustness of these findings in diverse settings and address a number of reported study limitations including failure to include quality of life and cost-effectiveness as outcome measures, lack of statistical power to detect important differences between groups, the lack of screening tools that demonstrate predictive validity, and poorly described interventions. A crucial stage towards evaluating a complex intervention is assessing the feasibility of both the intervention as well as the mechanisms for its evaluation (8). This proposed feasibility study will lay the foundation for a cluster randomized controlled trial that will address the identified limitations of research conducted to date (4,7,9) by incorporating the following features: 1) targeting community dwelling older adults with multi-morbidity; 2) screening older adults (≥ 70 years) at risk of functional decline using a tool of demonstrated predictive validity; 3) estimating adequate sample size to detect clinically important and policy relevant effects; 4) identifying a valid primary outcome measure that assesses quality of life; 5) and, developing an approach to economic evaluation to assess the cost-effectiveness of the intervention.

Plan of Investigation

Design and sample. We will perform a feasibility cluster randomized controlled trial where 8 primary care practises will be randomly assigned (4 facilities per arm) to the intervention group versus usual care alone. Randomisation will be stratified according to location (Northern Ireland /Republic of Ireland – Louth, Monaghan). Primary care practices will be randomly allocated to the intervention or usual care arm before patient screening for risk of functional decline. A total of 64 patients (32 per study arm, 8 patients, randomly selected, per primary care practise) will be enrolled into the study. A sample of 32 patients per study arm is considered adequate to allow the size of any definitive trial to be determined more accurately and therefore minimize the number of patients required overall (10,11).

Setting. Practices located in Northern Ireland will be recruited via the Northern Ireland Clinical Research Network (Primary Care). In the Republic of Ireland the HRB Primary Care Trials Network will recruit primary care practises located in the border counties of Louth and Monahan. Practises will be drawn from both urban and rural settings that serve a socioeconomically deprived population.

Patient inclusion and exclusion criteria. Research study nurses will facilitate computer searches on the GP database system to identify potential study candidates (12,13,14). Study inclusion criteria are: 1) aged ≥ 70 years; 2) in receipt of a valid general medical services (GMS) card in the Republic of Ireland, or for Northern Ireland registered for NHS primary care services; 3) ability to complete a postal questionnaire. Exclusion criteria: 1) receiving specialist palliative care; 2) record of assessed cognitive impairment at the level that would impact their ability to complete screening postal questionnaire, outcome measures and participate in a patient care conference(s) (defined as Mini Mental State Examination (MMSE) ≤ 20); 3) experiencing a

psychotic episode at the time of recruitment; 4) hospitalised long-term, in a nursing home, homeless or in sheltered accommodation.

Patient screening. Patients who meet the study inclusion criteria will be assessed for risk of functional decline through a three step process; 1) General Practitioner (GP) database search; GP staff will identify candidates who have two or more chronic medical conditions (*Note that hypercholesterolemia can be counted as a chronic condition for our purposes); four or more prescribed medications; and, availability of informal caregiver if recorded; 2) identified candidates will be reviewed by their own GP to confirm suitability for inclusion in the study; 3) Eligible candidates will receive a letter from their GP informing them about the project and inviting them to complete the PRISMA 7 questionnaire, a seven item questionnaire that includes items related to age, gender, mobility, need for assistance in activities of daily living and the availability of informal support (15). The instrument identifies frailty and is suitable for postal completion. The PRISMA 7 is considered a best practice tool that is recommended by NHS England to case find at-risk patients for frailty in general practice. Individuals who obtain a score of > 3 are identified as being at risk of functional decline (16,17). If there is no response to the initial letter, up to two more follow-up reminders will be mailed in one-week intervals (18).

Patient enrolment. Individuals who screen as at risk of functional decline will be sent a letter from their GP inviting them to participate in the study. A project research assistant will recruit consenting patients by telephone. Allocation to the intervention vs. usual care will be communicated to the study participant by a member of the research team after the research assistant has obtained consent and conducted the baseline-standardised interview. In the case of two or more eligible participants in any one household, all will be eligible for enrolment into the study. In the intervention arm the study nurse employed by the project will then commence arrangements to visit the appropriate patients.

Anticipatory care planning intervention (ACP). Personalised care and support planning is the framework for this intervention. A commitment by both the healthcare provider and patient to shared decision making is considered essential for personalised care planning (3,7). In shared decision-making, both parties must work together to understand problems, preferred goals and outcomes, sharing information and identifying options with the aim of reaching mutual agreement on the best course of action for the individual patient (3,7). Four main steps have been identified in the care and support process to promote a shared decision making approach (3,7,19): 1) prepare - starting from the patient and their family carer point of view gather necessary information, typically through patient assessment); 2) discuss - taking a partnership approach identify the actions that a person can take and what care and/or support might be needed from others; 3) document - the agreed support plan, owned by the patient and shared with consent; 4) review - consider options for follow up and set a date for review (19).

The nurse led ACP intervention will be integrated into regular care where the study nurse will involve the patients' GP in care planning and is informed about patients' goals and plans. As a first step in the intervention, the study nurse will contact the patient by telephone to schedule an initial home visit. This will typically be conducted within 4 weeks of the return of the participant's PRISMA 7 postal questionnaire. At the initial home visit the study nurse will, with the aid of a medical summary including current repeat prescription provided by the GP practice, will employ a structured protocol conduct a brief Comprehensive Geriatric Assessment (CGA) that will also encourage discussion about present and future care and patient goals. New guidance from the British Geriatrics Society (17) suggests that it is not feasible for everyone with frailty (from mild

up to severe, life-limiting frailty) to undergo a full multi-disciplinary CGA review with geriatrician involvement. Nevertheless, all patients at risk of functional decline can benefit from a holistic medical review based on the principles of CGA. Completion of the brief CGA will enable the development of both a problem and action list that will inform care planning.

Following the initial home visit the study nurse will draft a structured summary report of the home visit that will include patient goals, preferences for care, identified problems and action list. The study nurse will forward to a pharmacist, who will be an adjunct to the study, the summary report generated from the brief CGA highlighting the patient medication list and the identification of potentially inappropriate prescribing (PIP). The pharmacist will cross check and verify the presence of PIPs. A record will be maintained by the pharmacist on the accuracy of the study nurse identifying PIPs during the trial. The results of this audit will contribute to the finalisation of the intervention. Subsequent to PIP feedback from the pharmacist the study nurse will finalize the summary report and will meet with the GP who will be informed through a structured format patients goals and wishes, results of the patient assessment, problem list and recommended actions. The GP with appropriate participation of other members of the health care team, will review, provide feedback and confirm agreement with the plan of care.

In the second home visit the study nurse will meet with the patient and family carer to discuss identified problems, review proposed options for support, document the agreed support plan and consider options for follow up and set a date for review. The study nurse may conduct, depending on clinical need, the second visit in the patients' home or the GP practise so the GP can be present. The finalised care plan will be left with the patient and a copy will be placed in the patient's chart in the GP practise. Throughout the intervention, participants will be encouraged to take an active part in their health care. While the number and frequency of visits will vary by the needs of participants, it is expected that participants in the intervention group will receive up to 5 hours of nursing contact over 6 months of the intervention. This will include two home visits per patient, as well as telephone contacts with the patient, and meeting(s) with the GP and contacts other health and social care providers.

Usual care group. Patients in the usual care group will not receive the ACP intervention but will receive usual care from their GP. The PRISMA 7 score with an explanation will not be sent to the GP in the usual care group.

Training. Study nurses from both jurisdictions will receive combined training in Belfast. Training will take place over three days. The first day will include an overview of the study, principles and practise of personalised care, shared-decision making and comprehensive geriatric assessment (CGA). The second day will be on medications review and the identification of potential inappropriate prescribing. The third day will include shadowing patient CGA conducted by a skilled nurse from the department of Older People's Services, Belfast Health and Social Care Trust (BHSCT). The development of the training module will include a review of resources and protocols relevant to both Northern Ireland and the Republic of Ireland.

Methods of data collection and methods of data analysis.

The RE-AIM conceptual framework will guide considerations for the evaluation of the ACP intervention (20-22). Four of the five factors included in the RE-AIM framework apply to the parameters of the proposed study: 1) Reach - describes the number, proportion and representativeness of primary care practises and patients who participate in the initiative; 2) Effectiveness – the impact of the intervention on outcomes; 3 Adoption – the willingness of primary care practises exposed to the intervention who are willing to initiate the intervention;

and 4) Implementation – fidelity of intervention protocol and consistency of implementation across primary care practises and jurisdictions. Maintenance usually refers to on-going implementation into routine care for at least 2 years post-intervention, and is therefore beyond the scope of this feasibility study.

Patient standardized interview (RE-AIM Effectiveness factor)

On obtaining consent from the patient to participate in the study, a baseline patient standardized survey interview will be conducted by a trained project research assistant in the home. In order to assess the impact of the intervention, all patients will participate in the individual standardized survey interviews at baseline, six week and six month follow-up. Home Interviews are estimated to be 45 minutes to one hour in duration.

Baseline measures

Information on variables expected to predict responsiveness to the intervention (demographic factors, social support, medical conditions, prescribed medications, and cognitive impairment) will be obtained during the initial (baseline) in-person interview by a research assistant.

a) Demographic data. Demographic data will include age, gender, education, living arrangements, income and economic resources.

b) The Medical Outcomes Study Social Support Survey (MOS) (23). Is a 20-item instrument designed for use with chronically ill patients. It assesses four categories of social support; tangible support, affectionate support, positive social interaction, and informational support. Respondents use a Likert-type scale to rate each item ranging from 'None of the Time' to 'All of the Time'. Psychometric properties are sound having good reliability, internal consistency and construct validity.

Outcome Measures

All outcome measures will be assessed at baseline, six weeks and six months. All selected measures have been used on this population in previous research as both outcome and observational measures (24,25,26)

Primary outcome measures (RE-AIM – effectiveness factor)

a) EQ-5D-5L (27) Is a widely used self-reported generic measure of health reported quality of life that has been validated in different patient populations. The five-level version contains the same dimensions as the earlier three-level version but has been designed to provide greater reliability and sensitivity.

b) Center for Epidemiological Studies Depression Scale (CES-D) (28) This 20- item scale has been used extensively with older adults. Respondents use a four choice scale to rate how they have felt in the past week expressing depressed mood.

Secondary outcome measures (RE-AIM - effectiveness factor)

a) Patient Assessment of Chronic Illness Care (PACIC) Scale (29) This 20 item scale was designed to assess from the patient perspective the receipt of patient-centered care and self-management behaviors.

b) Health Economic Evaluation. The health economic analysis will consist of trial-based economic evaluation and will incorporate both cost effectiveness analysis and cost utility analysis to compare the alternative treatment strategies: (1) the Anticipatory Care Planning (ACP) Intervention; and (2) usual care in general practice. The basic tasks of the evaluation are to identify, measure, value and compare the costs and outcomes of the alternatives being considered. Evidence collected on resource use and outcome measures alongside the trial will provide the basis for the analysis over the trial follow up period. With respect to costing, a health service perspective will be adopted. Resource use associated with delivery of the ACP Intervention will be measured and costed. Other resource use to be captured will include usage of medications, primary care, community care, and hospital care services. Unit costs will be applied to convert data on resource use to resource costs and total cost variables will be calculated. As detailed above, significant attention will be paid to collecting relevant data on health outcomes alongside the trial. For the cost effectiveness analysis, the treatment strategies will be compared on the basis of the effectiveness data for the primary outcomes of interest. For the cost utility analysis, effectiveness will be evaluated on the basis of Quality Adjusted Life-Years (QALYs) which will be estimated using the EuroQol EQ-5D-5L survey instrument. The health economic analysis will employ the standard approach for the comparison of alternative treatment strategies in terms of costs and health outcomes. An incremental analysis will be undertaken to provide information on the marginal costs and effects of the ACP Intervention relative to usual care through the calculation of incremental cost effectiveness ratios and incremental net benefits. Univariate, multivariate and probabilistic sensitivity analyses will be employed to address uncertainty in the study

c). Katz Index of Independence in Activities of Daily living (30). This well-established instrument is a measure of performance describing what the person does rather than what they are capable of doing. It assesses six activities: ability to bathe, dress, toilet, transfer, feed self and maintain bowel and bladder continence. A three-category scoring model is used for each activity.

d) Generalized anxiety disorder (GAD) (31) In the GAD patients are asked how often, during the last 2 weeks, they were bothered by 7 anxiety related symptoms.

e) Potential inappropriate prescribing (PIP) (32). Will be assessed on the proportion of patients with PIP drugs. We will assess the mean number of PIP drugs between the intervention and usual care groups.

2. Tracking intervention patterns and intensity (RE-AIM Implementation)

Records will be maintained describing the patterns and intensity of care provided to each participant in the intervention group. Nurses will maintain logs to record the amount of time spent with each participant including home visits, phone calls, and consultations with family physicians and other professionals.

3. Qualitative interviews (RE-AIM - Adoption)

User perceptions on the appropriateness, benefits, and convenience of the intervention will be recorded through qualitative interview approaches. Patient (n = 32) acceptability of the intervention will be assessed using several additional questions embedded in the structured interview schedule conducted on the six-week follow-up for participants in the intervention arm of the study. These questions will assess perceptions about the intervention in terms of: (a) the overall intervention; (b) its component parts (the patient meetings, assessment, patient

education on advance care planning); (c) implementation (was the home environment suitable for meetings); (d) were the contents reviewed in the meetings useful; and (e) suggestions for refining the intervention (change the format of the meeting). The study nurses (n = 4) will also be interviewed on aspects of the intervention reviewing: (a) what experience a registered nurse should have to fulfill the position; (b) training requirements; (c) how to build relationships with participants; (d) if the home environment was suitable for the meetings; (e) if the ACP model fitted into the running of a GP practice; (f) their best and worst experience related to ACP meetings; and (g) the recommendations they would make to improve the ACP intervention. GP practice staff (GPs and associated healthcare providers) (estimate n = 12) will also have a brief interview that will examine perceptions on the appropriateness, benefits, and convenience of the intervention. Community health professionals (estimate = 12) will be interviewed to identify the facilitators and barriers that reside at the regional system level that may influence how the intervention is implemented.

4. Metrics to be collected (RE-AIM - Reach).

Records will be maintained that will collect indicators on: (a) number of eligible participants identified on the GP patient list; (b) number of participants found to be ineligible and reasons why; and (c) number of eligible participants who consent to participate and reasons for non-participation. Nurses in the intervention group will maintain logs to record the amount of time spent with each participant including home visits, phone calls, and consultations with family physicians and other professionals.

Analyses. Quantitative analysis: data will be expressed as a mean, standard deviation (SD) or median (minimum-maximum) for continuous variables and count (percent) for categorical variables. The analysis of indicators will be based on descriptive statistics reported as estimates with confidence intervals. Outcome analyses will be conducted to compare the intervention and control groups, recognizing that this analysis will be underpowered for statistical analyses. Means and SD will be reported for each combination of baseline-final data. Frequency and percentage will be reported in the same manner for categorical variables. The standard deviation of the change in primary outcome EuroQol EQ-5D-5L at six months will be determined and the intra cluster correlation of this change will be estimated to inform the sample size required for the main trial. The recruitment and retention rates at 6 months will also be determined to inform the sample size calculation. The investigators will also consider acceptability of the mode and timing of the administration of impact measures. Incremental cost effectiveness and cost utility analyses will be conducted for the purposes of the economic evaluation. All quantitative analysis will be conducted in a manner consistent with guidelines for the analysis of data from cluster RCTs. Qualitative analysis: the qualitative software program, NVivo 10.0 (33) will be used to help organize and analyze the data. We will analyze interview data following the template analysis style outlined by Miles and Huberman (34) and will develop an open-ended and modifiable codebook (template). We will use this tool to generate themes, patterns, and interrelationships in an interpretive fashion, drawing on the expertise of our research team and our Public Involvement Panel.

Criteria for progression to a full trial. A protocol for a full trial will be developed if the study findings demonstrate that the ACP intervention is acceptable to most (> 70%) patients, their carers and to health professionals; if the ACP can be readily implemented; if recruitment (> 35% GP practices, > 50% patients), and > 65% patient retention rate will likely be adequate for a full trial; if there is a detected change in the primary and secondary expected outcomes between

the intervention and usual care group; and, the features of the economic evaluation (35).

Existing research infrastructure. The project will be maintained in the School of Nursing and Midwifery (SNM) Queen's University Belfast. The study will have two governance bodies Project Management Team (PMT) (KB, PH, GC, KM, FD, EW, TF, PD) that will meet every two months and a Study Steering Committee (SSC) that will meet bi-annually. KB will head the PMT as chief investigator with overall responsibility for the research project and will oversee day-to-day research work by the research fellow. The PMT will present progress and findings to the SSC and consult its members. Collaborative dialogue between PMT and SSC (via project progress reports and bi-annual meetings, and on a frequent ad hoc basis) will facilitate consideration of how best to translate research findings into service improvements, ensuring healthcare service context and patients and staff needs are considered. A Public Involvement Panel (PIP) for family carers and older adults living with chronic conditions will be established. The panel will contribute to the development of the training module for study nurses, and interpretation of study data collection.

Ethical and governance approvals. In Northern Ireland ethics approval will be obtained from the Office of Research Ethics Committee Northern Ireland (ORECNI) and governance from the Queen's University Belfast Research Governance Office. In the Republic of Ireland application will be made to the Irish College of General Practitioners (ICGP) Research Ethics Committee.

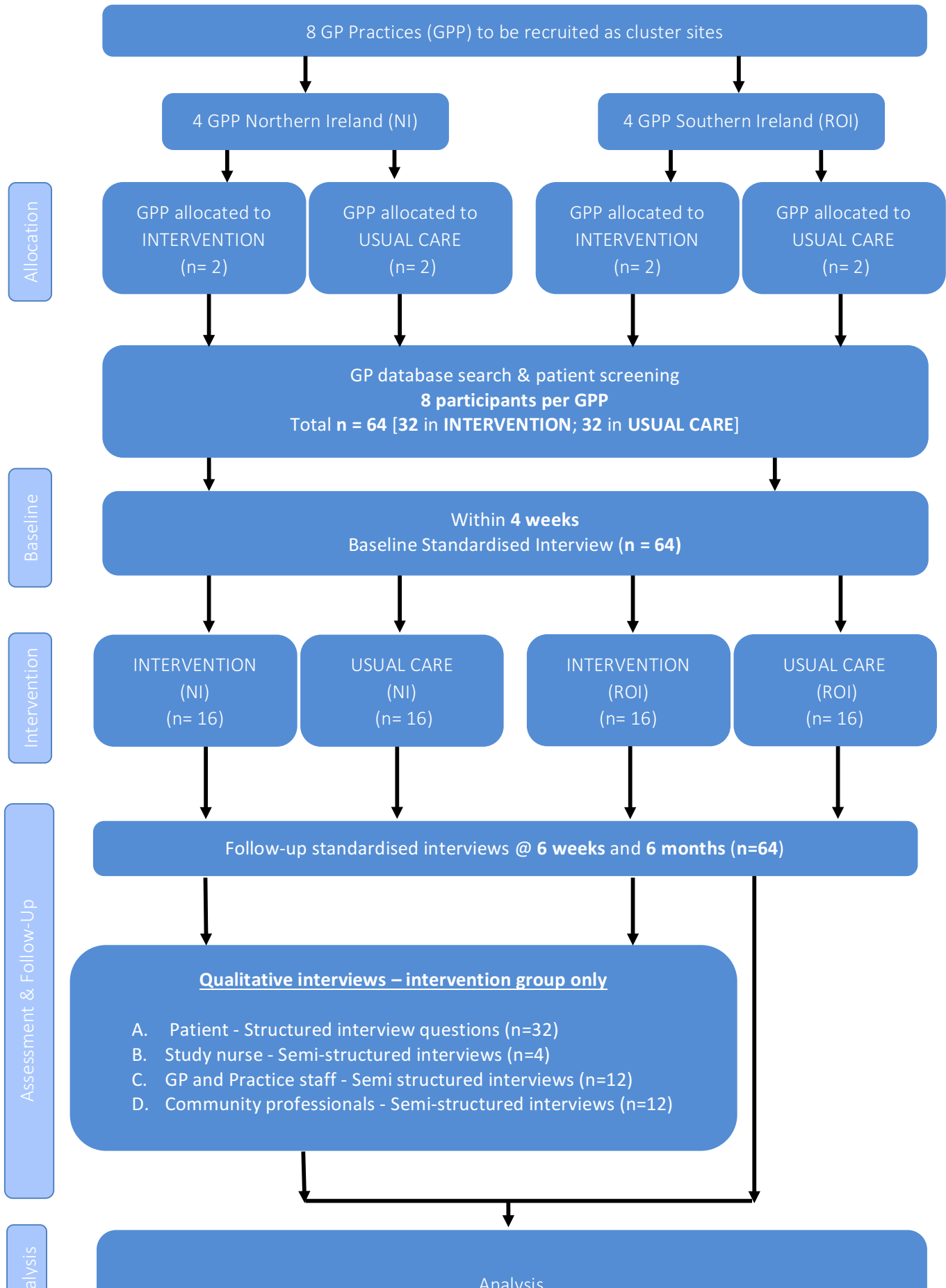
Dissemination and knowledge transfer plan. Our research team members will be well positioned to disseminate project awareness, and outcomes to the broader research and practice/ policy community. Dissemination products will be held on a project website hosted by the School of Nursing and Midwifery QUB website. Social media such as twitter and the use of a blog will also be developed. Academic dissemination will include submissions to conferences (e.g., Irish Gerontological Society Annual Conference, Society of Academic Primary Care Conference UK) and peer review journals (e.g., Age and Aging, BMC Family Medicine).

Envisaged outcome for future work. Based on the outcomes of the project we anticipate that we will target the Health Research Board and National Institute for Health Research, Health Services and Delivery Research programme in the winter of 2019 to fund the implementation of a national trial.

Timetable and milestones

Activity / Months	1-4	4-8	8-12	12-16	16-20	20-24
Application for ethics approval						
Secure Research Staff (Research Asst. ½ time for 14 months)						
Develop research training module						
Train Research Nurse(s) in ACP						
Finalize GP Practice enrolment to study						
Recruit patients						
Patients/Family Carers – standardised interviews (baseline & follow-up)						
Intervention implementation						

Quantitative data input and analysis						
Qualitative interviews and analysis						
Final analysis & report write-up						
Project management team meetings (bi-monthly)						
Study Steering Committee meetings x 4 (Quarterly)						
Knowledge transfer \ develop grant proposal for full trial						

STUDY DESIGN FLOW CHART

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